ANGIOPLASTY BALLOON FABRICATION WITH COMPOSITE MATERIALS

Invention Disclosure Second Draft (July 15, 2001)

ABSTRACT

Angioplasty balloons are required to be able to withstand very high pressures, which force the balloon's surface against various tissues and deposits representing a range of viscoelastic characteristics, and include some very hard and rough surfaces. As the balloons must be thin-walled to collapse into a small cross-section for introduction to the target area, the balloons must be made extremely strong and puncture resistant. The balloons also must expand in a predictable manner when the internal pressure is beyond the nominal value where the cross-section is rated. To meet these exacting requirements this patent disclosure presents a number of methods of creating composite films of organic polymers and inorganic additives on a nanometric scale. The preparation and formation of balloons using specifically carbon nanotubes and clay platelets is presented.

BACKGROUND

Angioplasty addresses the problems of partially or fully obstructed arteries. Angioplasty balloons have been used by invasive cardiologists since the 1970s when Andreas Grunzig reported his data on reopening the occluded coronary arteries of five patients and that these arteries remained patent, open, allowing blood flow for six months or longer. The Grunzig procedure involved the introduction of a high-pressure angiographic catheter with a collapsed polymer balloon cemented to its distal portion. Once the catheter is positioned within the occluded range in the artery under fluoroscopic control, the balloon is pressurized, typically by injecting a fluid. The pressure in the balloon exerts pressure on the surrounding obstructive structures and enlarges the lumen, the cross section for blood flow. The balloon is depressurized until it collapses and it then can be withdrawn from the obstructed site where circulation has been restored through this maneuver.

As angioplasty, the reforming of blood vessels, has gained acceptance and replaced to a great extent the coronary artery bypass graft procedure, a major surgical intervention, the demands for the performance of the balloon catheter have increased. These demands include high strength to withstand pressures on the order of 10 to 20 atmospheres. In comparison, the typical passenger car's tires are inflated to about 32 psi or slightly above 2 atm. above the ambient pressure. While the typical tire wall is a composite, the walls are reinforced by high strength weaves of polyester filaments or stainless steel wires embedded in



CONFIDENTIAL INVENTION DISCLOSURE

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ANGIOPLASTY SUPER BALLOON FABRICATION WITH COMPOSITE MATERIALS

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(Final Draft) (18 July 2001)

ABSTRACT

Angioplasty balloons are required to be able to withstand very high pressures, which force the balloon's surface against various vessel tissues and deposits representing a range of viscoelastic characteristics, and include some very hard and rough surfaces. As the balloons must be thin-walled to collapse into a small profile (cross-section) for introduction to the target area, the balloons must be made extremely strong and puncture resistant. The balloons also must expand in a predictable manner when the internal pressure is beyond the nominal value where the cross-section is rated. In additions, balloon catheters are also used to deploy metallic stents within a constricted vessel. Stents are expandable wire mesh devices that help retain proper vessel lumen after dilation. In this application, the balloon must come in contact with a metallic mesh that may inflict damage to the balloon. To meet these exacting requirements this intellectual property disclosure presents a number of methods of creating composite films of organic polymers and inorganic additives on a nanometric scale. The preparation



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